



Drug Research Unit Ghent (D.R.U.G.)

The Early Phase Clinical Drug Research Unit of the University
Hospital Ghent



Mission statement

To contribute to the **development** of new drugs by conducting clinical trials (majority of them **early phase**) in **healthy subjects** as well as in **adult patients**.

Since 2018 the Drug Research Unit Ghent contributes also to the development of new drugs by conducting clinical trials in **pediatric patients** in close collaboration with the pediatric department of the University Hospital Ghent.

In compliance with international legislation and quality standards.

Milestones



- ▶ 2001: Founded by Prof. dr. L. Van Bortel
- ▶ 2003: ISO 9001:2000 certified
- ▶ 2005: Contribution to development of drugs for developing countries
- ▶ 2006: Preferred partnership contract with global pharma industry
- ▶ 2009: ISO 9001:2008 certified

Milestones



- ▶ Part of Oncology care program initially
- ▶ NOV 2008: approval of the Phase I Unit Oncology by the medical board of the hospital; ISO 9001:2008 certified
- ▶ JAN 2009: approval of the Phase I Unit Oncology by the board and the CEO of the Ghent University Hospital
- ▶ From JAN 2011 on: 4 Key Activities supported by the hospital (Oncology, Clinical Immunology, Genetics & Neuroscience)

Milestones



- ▶ 2014: Close collaboration in between both units
- ▶ AUG 2015: New facilities on the campus
- ▶ OCT 2015: Official merging of D.R.U.G. and Phase I Oncology
- ▶ Until 2017: ISO 9001:2008
- ▶ 2018-2019: integration in hospital accreditation, NIAZ/Q-Mentum
- ▶ National accreditation Phase I pending
- ▶ 2018: start of pediatric clinical trials

Milestones



- ▶ Automatisatation of procedures
- ▶ FAGG accreditation of phase I unit
- ▶ 2024: Move to Nobel I building

Expertise

Healthy subjects

- ▶ First in man, SD
- ▶ First in man, MD
- ▶ Phase-0 studies (eCTA) and proof of concept
- ▶ Biomarker/surrogate marker development
- ▶ Food/Drug interaction
- ▶ Bioequivalence
- ▶ Biologicals
- ▶ Special groups (hypertensives, elderly, postmenopausal women)
- ▶ Cardiovascular: telemetry, BP, arterial function & structure

Oncology

- ▶ First in man, dose escalation
- ▶ First in man, expansion cohorts
- ▶ Medical devices
- ▶ Interaction studies
- ▶ Biomarker studies
- ▶ QT studies
- ▶ Fresh biopsies
- ▶ Small molecules
- ▶ Immunotherapies
- ▶ CAR-T cell studies
- ▶ NGS based clinical trials

+ Patient studies for other hospital departments and other principal investigators

Referral of patients for Phase I Oncology Trials : analysis of 34 patients in MAY 2022 in our Phase I unit treated

Medische Oncologie UZGent	13
Gastro UZGent	4
UZLeuven	5
Moeskroen	1
AZ St Lucas Brugge	1
AZ Delta Roeselare	1
AZ Groeninge Kortrijk	2
AZ Sint Jan Brugge	2
Veurne	1
OLV Aalst	1
Waregem	1
Ronse	1
AZ Damiaan	1

Stipulations

High Quality

Quality control - Quality assurance

Quality management system - Document management

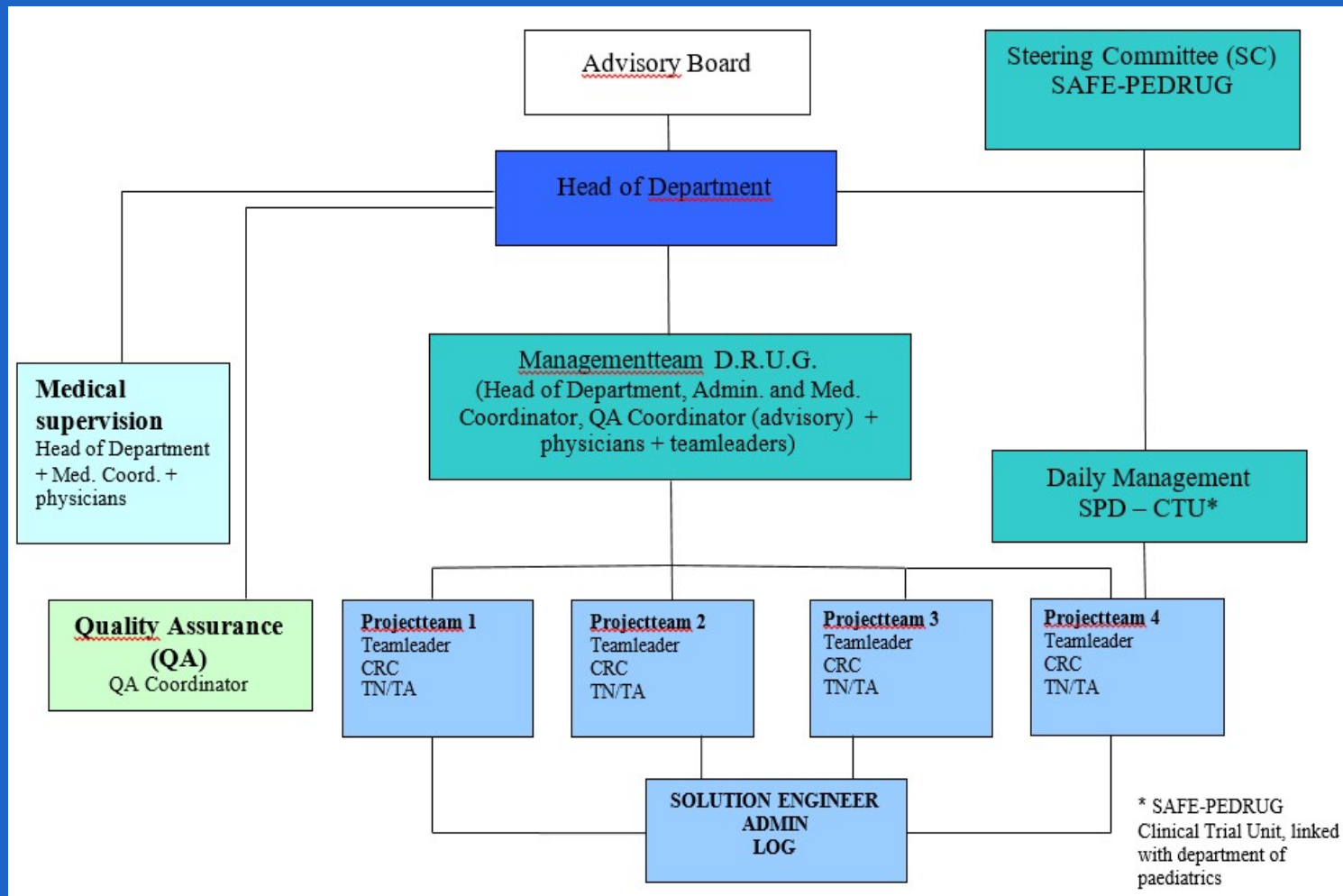
Training employees

Apparatus: temperature management and control – Calibrated devices

FDA - FAGG Inspections

Second party audits

Staff



Facilities

- ▶ 20 beds for overnight stay
- ▶ Telemetry for 15 subjects
- ▶ 2 clinical laboratories (temperature controlled)
- ▶ 1 sample handling laboratory (temperature controlled)
- ▶ 1 drug storage room (temperature controlled/alarm)
- ▶ 3 freezers (-20°C) + 1 freezer (-70°C) (temperature controlled/alarm)
- ▶ 6 refrigerators
- ▶ Wifi network
- ▶ Canteen, recreation room, offices, reception, meeting room, monitor room, storage rooms and kitchen
- ▶ Biosafety level 1

For healthy subjects / patients

- ▶ **Overnights and measurements in separate rooms**
(2 subjects/room for the night)
- ▶ **A group of 34 staff members**
(except for the nights which are done by Assistant Trial Nurse)
- ▶ **4 investigators close on the spot**
(24h/24h availability)

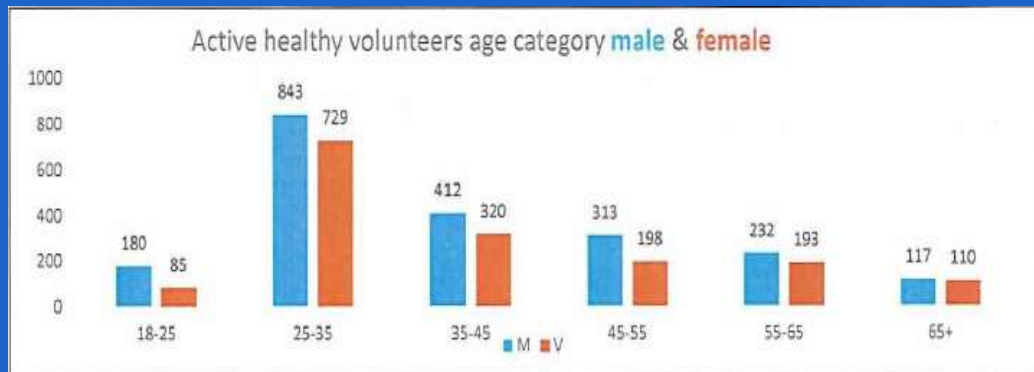
Sponsors

- ▶ Pharmaceutical industry (majority)
- ▶ University
- ▶ University hospital

Recruitment

Healthy subjects

- ▶ Database with +/- 3800 active subjects (including patient-subjects)
- ▶ VCT (Verified Clinical Trials) prevents concurrent participation in multiple trials.
- ▶ Recruitment by e-mail and (online) advertisement



Patients

- ▶ **Internally:**
Inclusion on a multidisciplinary basis, which is reflected by the composition of the Phase I working group of the hospital. Patients come from different departments: Medical oncology, GI oncology, pneumo-oncology, hematology...
- ▶ **Externally:**
 - ▶ Patients are referred on a regular basis from > 25 different hospitals
 - ▶ List of running clinical trials is sent on a regular basis to medical doctors involved in oncology in Flanders

Embedding in University Hospital Ghent





Phase I Oncology Working Group

- ▶ 4x/year meeting
- ▶ Discussion about trials (new and ongoing), listing side effects, recruitment issues, operation of the department,...
- ▶ Different oncology disciplines are represented next to the head of the department Prof. Dr. Rottey:
 - ▶ Cancer Centre UZ Ghent
 - ▶ Gastroenterology
 - ▶ Pneumology
 - ▶ Hematology
 - ▶ Medical Oncology
 - ▶ Radiation Oncology
 - ▶ Gynecology
 - ▶ Pathology
 - ▶ Pharmacy
 - ▶ Research physicians D.R.U.G. + 1 team leader of D.R.U.G.



Poli Medical Oncology

- ▶ 1st contact with patient interested in inclusion in Phase 1 trial
- ▶ Patient is informed about Phase I trials in general
- ▶ Patient is put on **waiting list** if no slot for trial is available

Day hospital and hospitalization Medical Oncology

- ▶ **Patient Care**
- ▶ **Day hospital**
 - ▶ **Blood transfusion**
- ▶ **Hospitalization:**
 - ▶ **Hypercalcemia**
 - ▶ **Neutropenic sepsis**
 - ▶ **Start up of parenteral nutrition**
 - ▶ **Optimization pain medication**
 - ▶ **Serious adverse events (SAE)**
 - ▶ ...



Ethics Committee

For all Phase I trials in oncology, protocols are explained in person to the EC by Prof. Rottey

HIRUZ

- ▶ HIRUZ is the Health, Innovation and Research Institute of the Hospital in collaboration with Ghent University
- ▶ HIRUZ facilitates the various individual aspects of translational biomedical research in an integrative manner



Intensive Care Unit and Emergency Department

- ▶ Interested in drug development existing in our unit
- ▶ Willing to take care of our patients if needed

Pharmacy

- ▶ A separate Clinical Trial Unit within the Pharmacy Department of the hospital
- ▶ Storage of study medication
- ▶ On site formulations
- ▶ Packaging of study medication
- ▶ Reconstitution of study medication
- ▶ Preparation of IV study medication
- ▶ Ordering and delivery of study medication
- ▶ Improvement of collaboration by performing audits by each other



For study related assessments/follow up study patients

- ▶ Laboratory (safety testing)
- ▶ Radiology (CT, MRI)
- ▶ Nuclear Medicine (PET-CT, bone scan, MUGA scan, ...)
- ▶ Ophthalmology (ocular AE's)
- ▶ Dermatology (skin toxicities)
- ▶ Cardiology (echocardiography)
- ▶ Pathology (tumor tissue)
- ▶ Pneumology (lung function)
- ▶ Neurology (EEG)
- ▶ Anaesthesiology (high risk medication)
- ▶ Radiotherapy (antalgic radiotherapy)
- ▶ Interventional radiology (specific study drug administrations)
- ▶ Genetics (NGS sequencing)
- ▶ ...



Biopsy samples (archived and fresh)

Fresh Biopsy Sampling

- ▶ Ultrasonography (liver biopsies)
- ▶ EUS-EBUS (thoracic/mediastinal biopsies)
- ▶ Plastic surgery (skin)
- ▶ Dermatology (skin)
- ▶ Head and Neck Department (biopsies head and neck region)
- ▶ Interventional radiology (Image guided biopsies)

Pathology Department

Handling of biopsy samples

- ▶ Preparing slides of archived tissue
- ▶ Handling of fresh biopsy samples following specific instructions:
- ▶ Diagnosis
- ▶ Paraffin embedding
- ▶ Preparing slides
- ▶ Freezing
- ▶ Genetic analysis
- ▶

Phase I Oncology Trials 2021

Patients	Mandator	Number of Trials	PI
Cancer patients	Industry (20# sponsors)	40	S. Rottey

+ 1 observational trial

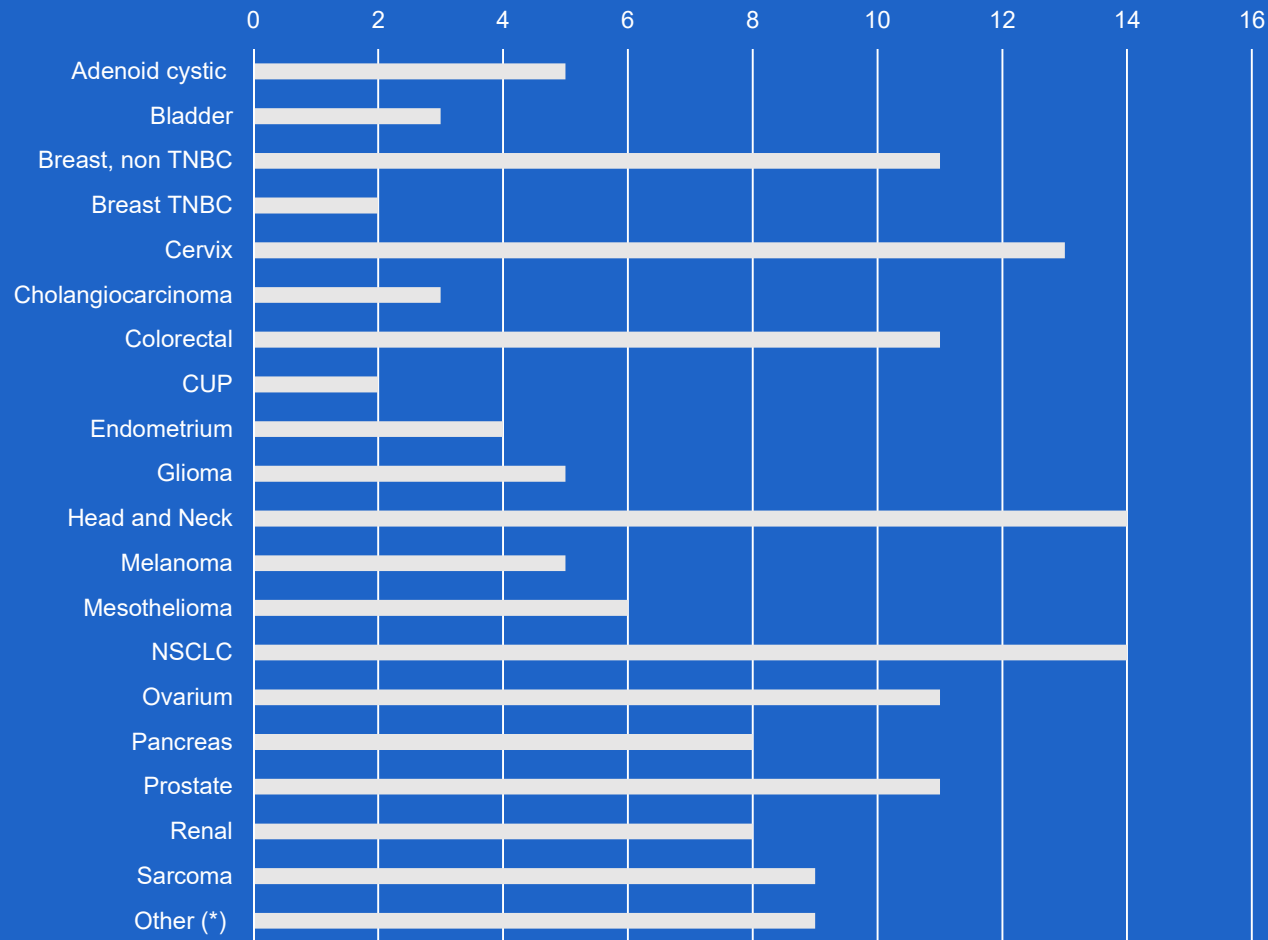
Subjects registered for Phase I Oncology trials in 2021: 118

Subjects in trial in 2021:

- ▶ 141 patients were prescreened for FoundationOne
- ▶ 10 patients were prescreened for MAGE-A1
- ▶ 28 ongoing subjects from 2020
- ▶ 46 subjects signed main ICF

Phase I Oncology Trials 2021

Diagnoses subjects registered for Phase I Oncology trials in 2021 (154 subjects)



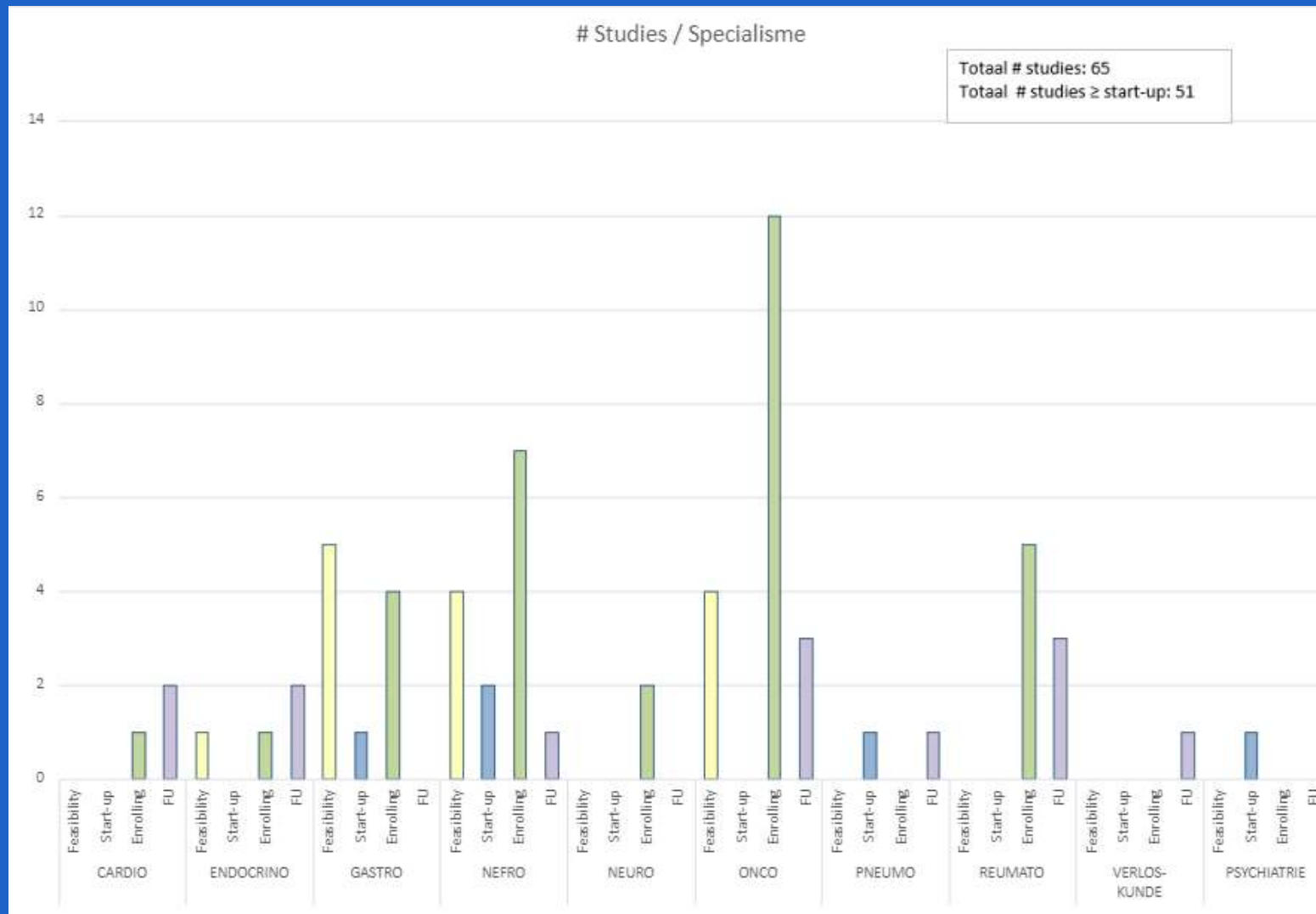
Other includes rare tumor types or which presented only once: adrenal gland carcinoma, *GEJ carcinoma*, *SMARCA4-deficient thoracic syndrome*, *testis carcinoma*, *thymus carcinoma*, *vaginal carcinoma*, *SCLC*, *stomach carcinoma*, *neuroendocrine lung carcinoma*

Phase I Trials in Healthy Subjects 2021

Type	Mandator	Number of Trials	Number of Randomized Healthy Subjects	PI
First in Humans	Industry	3	96	S. Rottey
Other studies	Industry	4	103	S. Rottey

Paediatric Trials – SPD-CTU

Snapshot of trials in SEP/2022



Summary

Centre of Excellence:

- ▶ Qualified staff
- ▶ Approval system – double control
- ▶ External audits
- ▶ Accreditation phase I unit pending

Short timelines

Takes advantage of University Knowledge Centre / embedding in a University Hospital environment

Clinical Research Centers on UZ Campus

Center for Vaccinology (CEVAC)

- ▶ Mission: Contribute to the development of new vaccines and the improvement of existing vaccines for the prevention or treatment of infectious diseases
- ▶ Conduct of Clinical Vaccine Trials (Phase I, II, III) in dedicated Clinical Unit and Immuno-Monitoring Lab (CEVAC CORE lab)
(University Hospital Ghent and University Ghent)
- ▶ Founded in 1986 and gained experience since then in over 200 clinical vaccine trials.
- ▶ Experienced, GC(L)P trained team of MD's (4), coordinators (2), project managers (2), study nurses (5), lab technicians (15) and a QUA-team (2)
- ▶ Large database of > 11000 healthy volunteers (adolescents, adults, elderly)

Memberships investigator



Prof. Rottey is President of BSMO
Board Member of Haelixia
Board member of BMUC

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